Research & development

As of May 9

■Pipeline of prescription pharmaceuticals (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
diquafosol sodium	DE-089	Dry eye	Merck Sharp & Dohme Corp. (U.S.)	China						Sep-2018

A dry eye treatment which stimulates secretion of mucin and aqueous components from the corneal and conjunctival epithelium. Its mechanism of action is different from existing treatments. Launched in December 2010 in Japan. Launched in October 2013 in Korea. Launched in February 2016 in Vietnam. Launched in April 2016 in Thailand. Currently seeking sequential approvals for marketing in Asia. Launched in September 2018 in China.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
sirolimus	DE-109	Uveitis	Original	U.S.						
				Japan						
				Europe						
				Asia				Apr-2015		

An intravitreal injection with immunosuppressive effect, anti-angiogenic effect, etc. Started an additional Phase 3 in December 2018 and planning to complete in January ~ June 2021 in the U.S. NDA filed in April 2015 in Asia.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
tafluprost/ timolol maleate	DE-111	Glaucoma/ Ocular hypertension	Co-development with AGC	China						

A fixed dose combination drug of a prostaglandin F2α derivative and a beta-adrenergic receptor blocker. Launched in Japan in November 2014. Launched successively in European countries since January 2015. Launched successively in Asian countries since April 2016. Started Phase 3 in January 2019 and planning to complete in the 1st half of FY2020 in China.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
epinastine hydrochloride	DE-114A	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan				Sep-2018		

An H_1 receptor antagonist with membrane-stabilizing function, as treatment for allergic conjunctivitis. High dose drug. Filed for manufacturing and marketing approval in September 2018 and planning to receive approval in July ~ December 2019 in Japan.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
omidenepag isopropyl	DE-117	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.						
				Japan						Nov-2018
				Asia				Apr2019		

An EP2 receptor agonist with a new mechanism of action. Started Phase 3 in September 2018 and planning to complete in January ~ June 2020 in the U.S. Launched in November 2018 in Japan. Filed for marketing approval in Korea in April 2019 with successive filings in Asian countries and planning to receive approvals starting from the 1st half of FY2020.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
carotuximab	DE-122	Wet Age-related macular degeneration	TRACON Pharmaceuticals	U.S.	(Phase 2a)					

An intravitreal injection of anti-endoglin antibody. Started Phase 2a in July 2017 and planning to complete in the 2nd half of FY2019 for development in the U.S.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
sepetaprost	DE-126	Glaucoma/ Ocular hypertension	ONO PHARMACEUTICAL	U.S.	(Phase 2b)					
				Japan	(Phase 2b)					

A prostaglandin analogue eye drop drug product with a novel mode of action that is both FP and EP3 receptors dual agonist for the treatment of glaucoma and ocular hypertension. Started Phase 2b in July 2017 in the U.S. and Japan.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
atropine sulfate	DE-127	Myopia	Singapore Health Services, Nanyang Technological University	Japan						
				Asia						

Muscarinic antagonist which reduces juvenile myopia progression. Planning to start Phase 2/3 in the 1st half of FY2019 in Japan. Started Phase 2 in November 2017 and planning to complete in the 2nd half of FY2019 in Asia.

—	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
glaucoma implant device	DE-128	Glaucoma	Original	U.S.			(Phase 2/3)			
				Europe						

A drainage implant device designed to lower and sustain intraocular pressure (IOP) for the treatment of primary open-angle glaucoma through the drainage of aqueous humor. Conducting Phase 2/3 in the U.S. and Europe in advance of application to FDA. Planning to complete PMA rolling submission in 2019 and launch in 2020 in U.S. Received CE Mark in Europe.

■Pipeline development status (clinical stage)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	DE-076C (Vekacia)	Vernal keratoconjunctivitis	Original	Europe					Oct-2018	
				Asia				Nov-2018		
				Others					Dec-2018	

An ophthalmic emulsion which improves vernal keratoconjunctivitis by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue penetration. Received the Marketing Authorization Application approval from the European Commission Agency in July 2018 and launched in October 2018 in U.K. Filed for manufacturing and marketing approval in November 2018 and planning to receive approval in July ~ December 2019 in Asia. Received marketing approval in December 2018 and planning to launch in 2019 in Canada.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
latanoprost	DE-130A (Catioprost)	Glaucoma/ Ocular hypertension	Original	Europe						
				Asia						

An ophthalmic emulsion of a prostaglandin $F_{2\alpha}$ derivative, for the treatment of glaucoma and ocular hypertension.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
intraocular lens	MD-16	Cataract	Oculentis	Japan						

A toric intraocular lens which be implanted into an aphakia after cataract surgery. Completed Phase 3 in April 2019 and planning to file in the 1st half of FY2019 in Japan.

■Changes from Q3 FY18 (February 5, 2019)

Dev. code	Changes
DE-117	Filed for marketing approval in Korea in April 2019 with successive filing in Asian countiries.
DE-130A	Started Phase 3 in April 2019 in Europe and Asia.
MD-16	Completed Phase 3 in April 2019 in Japan.